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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/694,586	10/27/2003	Ekambar R. Kandimalla	HYB-005US5	3762

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EXAMINER	
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ART UNIT	PAPER NUMBER
1648	
MAIL DATE	DELIVERY MODE
05/25/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/694,586	KANDIMALLA ET AL.	
	Examiner	Art Unit	
	MICHELLE HORNING	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 March 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20,21,41,46 and 47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20,21,41,46 and 47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 October 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This action is responsive to communication filed 3/9/2010. Claims 20, 21, 41, 46 and 47 are under current examination.

To allow entry of the rejections below, this action is non-final.

Any rejection(s) not reiterated herein has been withdrawn.

Terminal Disclaimer

The terminal disclaimers filed on 3/9/2010 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of 7262286, 7405285, 7427405, 7470674, 7498425, 7566702, 7595305, 7517862 and 7407944 have been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 20, 21, 46 and 47 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are drawn (in part) to an immunostimulatory oligonucleotide compound comprising a C*pG, C*pG*

or CpG* wherein G is a natural purine nucleoside and G* is a non-natural purine nucleoside.

The following quotation from section 2163 of the MPEP is a brief discussion of what is required in a specification to satisfy the 35 U.S.C. 112 written description requirement for a generic claim covering several distinct inventions:

> The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice (see i)(A), above), reduction to drawings (see i)(B), above), or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus (see i)(C), above). See Eli Lilly, 119 F.3d at 1568, 43 USPQ2d at 1406.
>
> A "representative number of species" means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus.

Thus, when a claim covers a genus of inventions, the specification must provide written description support for the entire scope of the genus. Support for a genus is generally found where the applicant has provided a number of examples sufficient so that one in the art would recognize from the specification the scope of what is being claimed or through disclosure of a functional characteristic of the claimed genus coupled with a known or disclosed non-functional characteristic (structure) that correlates to the function.

As noted above, the claims are drawn to (in part) an immunostimulatory oligonucleotide compound comprising a C*pG, C*pG* or CpG* wherein G is a natural purine nucleoside and G* is a non-natural purine nucleoside and wherein C is a natural purine nucleoside. As claimed, the C, G and G* are not limited to cytosines or guanosines but to all natural pyrimidine nucleosides (e.g. uridine), all natural purine

nucleosides (e.g. adenosine) and all modified purine nucleosides (e.g. which may result in a caffeine, uric acid etc.).

While the claims are broad in view of a compound's structure, functionally the claims are limited to a compound that is immunostimulatory. The instant specification provides evidence that some replacements of the deoxynucleosides (e.g. 2'-methylribonucleosides) in a CpG motif can suppress immunostimulatory activity because such a modification does not allow for the proper recognition and/or interaction of the CpG-motif with the proteins required in the immunostimulatory pathway (p. 4, lines 5+). The instant specification further discloses that the precise structural requirements and specific functional groups of the CpG motif necessary for the recognition of protein/receptor factor that is responsible for immune stimulation have not yet been studied in detail (p. 5, lines 23+). Note that different functional effects would be expected for different structures and the different structures of an immunostimulatory compound comprising, for example, a non-natural purine nucleoside (G*) would be endless in structural possibilities. It is not clear from the instant specification what specific structures are required in order to retain the recognition and/or interaction with the proteins that are responsible for immune stimulation. Given no structure to function correlation is provided, the functional effects of a sequence comprising a C, G or G* in a CpG motif is unpredictable.

It is noted that the instant specification provides specific written description for 5-hydroxycytosine (p. 24), N4-ethylcytosine (p. 24) and 7-deazaguanine (Fig. 21) as modifications within the CpG motif.

Given the breath of the claims and the lack of structure to function correlations of an immunostimulatory compound comprising a C, G or G*, the claims are rejected for lacking written description support. The dependent claims fall herein.

Double Patenting-Maintained

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 20, 21 and 41 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 7713535. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to an immunostimulatory oligonucleotide compound or an intended use of such a compound wherein the compound comprises a C*pG, CpG* or a C*pG*, an internucleoside linkage and a 3'-3'

linker wherein the C*, C, G* or G are either naturally occurring or non-naturally occurring nucleosides.

Claims 20, 21 and 41 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No. 7709617. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to an immunostimulatory oligonucleotide compound or an intended use of such a compound wherein the compound comprises a CpG*, an internucleoside linkage and a 3'-3' linker wherein the G'is a 2'-deoxy-7-deazaguanosine which reads upon the scope of a 7-deazaguanosine.

Claims 20, 21 and 41 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2-4, 7, 8, 10, 11 and 13 of copending Application No. 11/174450. Note that a US Patent No. has not yet been issued. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to an immunostimulatory oligonucleotide compound or an intended use of such a compound wherein the compound comprises a CpG*, an internucleoside linkage and a 3'-3' linker wherein the G'is a 7-deazaguanosine.

Claims 20, 21 and 41 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4, 8, 10, 12, 14 and 15 of copending Application No. 11/641551. Note that a US Patent No. has not yet been issued. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to an immunostimulatory

oligonucleotide compound or an intended use of such a compound wherein the compound comprises a CpG*, an internucleoside linkage and a 3'-3' linker wherein the G'is a 7-deazaguanosine.

Claims 20, 21, 41, 46 and 47 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 37 and 39-56 of copending Application No. 11/906781. Note that a US Patent No. has not yet been issued. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to an immunostimulatory oligonucleotide compound or an intended use of such a compound wherein the compound comprises a C*pG, CpG* or C*pG*, an internucleoside linkage and a 3'-3' linker wherein the C*, C, G* or G are either naturally occurring or non-naturally occurring nucleosides.

Claims 20, 21,41, 46 and 47 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 18, 22, 26-28 and 35-41 of copending Application No. 10/865245 (20050026861). Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to an immunostimulatory oligonucleotide compound or an intended use of such a compound wherein the compound comprises a C*pG, CpG* or a C*pG*, an internucleoside linkage and a 3'-3' linker wherein the C*, C, G* or G are either naturally occurring or non-naturally occurring nucleosides.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 20, 21,41, 46 and 47 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 5, 16, 18-22 and 26 of copending Application No. 11/060228 (20050222072). Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to an immunostimulatory oligonucleotide compound or an intended use of such a compound wherein the compound comprises a C*pG, CpG* or a C*pG*, an internucleoside linkage and a 3'-3' linker wherein the C*, C, G* or G are either naturally occurring or non-naturally occurring nucleosides.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 20, 21,41, 46 and 47 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 11-13 and 16-17 of copending Application No. 11/153054 (20060014713). Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to an immunostimulatory oligonucleotide compound or an intended use of such a compound wherein the compound comprises a C*pG, CpG* or a C*pG*, an internucleoside linkage and a 3'-3' linker wherein the C*, C, G* or G are either naturally occurring or non-naturally occurring nucleosides.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 20, 21,41,42, 46 and 47 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 8-

10 and 19-38 of copending Application No. 10/892550 (20060074040). Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to an immunostimulatory oligonucleotide compound or an intended use of such a compound wherein the compound comprises a C*pG, CpG* or a C*pG*, an internucleoside linkage and a 3'-3' linker wherein the C*, C, G* or G are either naturally occurring or non-naturally occurring nucleosides.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 20, 21 and 41 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 7, 9-13, 16, 17, 19, 21, 23, 25, 27 and 33-37 of copending Application No. 11/641590 (20080279785). Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to an immunostimulatory oligonucleotide compound or an intended use of such a compound wherein the compound comprises a CpG*, an internucleoside linkage and a 3'-3' linker wherein the G'is a modified guanosine.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Note that the double patenting rejections have been updated and five of the applications have been allowed since the last action. Applicant notes that if a provisional nonstatutory ODP rejection is the only remaining rejection, these rejections should be

withdrawn. However, a new rejection has been made under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. Also, note that the judicially created doctrine of non- statutory double patenting is based on two preventative policies. The unjustified extension of rights granted and "to prevent possible harassment by multiple assignees" as noted by the form paragraph for nonstatutory double patenting (see above).

Double Patenting-New

Claims 20, 21 and 41 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 14-19 of copending Application No. 11/876913 (20080193437). Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to an immunostimulatory oligonucleotide comprising a CpG* wherein the G* is a 2'-deoxy-7-deazaguanosine which falls into the scope of a 7-deazaguanosine (instant claim 41) and a 3'-3' linker or the intended use thereof.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 20, 21 and 41 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 of copending Application No. 11/877767 (20090010938). Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to an immunostimulatory oligonucleotide comprising 5-hydroxycytosine and a

guanosine or other non-natural purine nucleoside (instant claim 20) and a 3'-3' linker or the intended use thereof.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 20, 21 and 41 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 2 of copending Application No. 12/168641 (20090053205). Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to an oligonucleotide comprising a CpG* wherein the G* is a non-natural purine and a 3'-3' linker.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 20, 21 and 41 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 22-28 of copending Application No. 12/565151. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to an immunostimulatory oligonucleotide comprising a CpG* wherein the G* is a 2'-deoxy-7-deazaguanosine which falls into the scope of a 7-deazaguanosine and a 3'-3' linker or the intended use thereof.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 20, 21 and 41 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1-10 of copending Application No. 12/592850. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to an immunostimulatory oligonucleotide comprising a CpG* wherein the G* is a non-natural purine and a 3'-3' linker or the intended use thereof.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 20, 21, 41, 46 and 47 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1-19 of copending Application No. 12/757425. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to an immunostimulatory oligonucleotide comprising a CpG wherein the G is a 2'-deoxy-7-deazaguanosine which falls into the scope of a 7-deazaguanosine (instant claim 41), a C is an arabinocytidine and a 3'-3' linker or the intended use thereof.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claim is allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHELLE HORNING whose telephone number is

(571)272-9036. The examiner can normally be reached on Monday-Friday 8:00-5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ZACHARIAH LUCAS can be reached on 571-272-0905. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/EMILY M LE/
Primary Examiner, Art Unit 1648

/M. H./
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